

### **REMARKS**

The pending Office Action addresses claims 20 and 22-40. Claim 35 is withdrawn and claims 20, 22-34, and 36-40 stand rejected. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

Applicants thank Examiner Ramirez for extending the courtesy of a telephone interview on September 17, 2009 to Applicants' representatives. Although no agreement was made during the interview, substantial progress was made in narrowing the issues remaining in prosecution.

#### ***Amendments to the Claims***

Applicants amend claim 20 to include the limitations of now-canceled claim 23. Claim 24 is amended to reflect the cancellation of claim 23. Claim 37 is amended to recite that the extracorporeal transmitter has a central opening formed therein and that the acoustic sensor is disposed within the central opening in the transmitter. Support for this amendment can be found throughout the specification and drawings, for example in paragraph [0049] and FIGS. 3A-4B. No new matter is added.

These amendments are made solely to expedite prosecution, and Applicants reserve the right to pursue claims the same as or similar to those originally presented.

#### ***Claim Rejections Pursuant to 35 U.S.C. § 103(a) - "Porat and Hakim"***

Claims 20, 22-30, 32, and 37 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,432,050 ("Porat") in view of U.S. Patent No. 4,595,390 ("Hakim"). Applicants respectfully disagree.

#### **Claim 20**

Independent claim 20 recites an acoustic monitoring device for verifying the pressure setting of a valve mechanism in an implantable device having a plurality of adjustable valve settings. The acoustic monitoring device includes *an extracorporeal housing having a top surface, a bottom surface, and a central opening*. The device also includes a transmitter contained within the housing having a plurality of electromagnetic coils configured to generate an energy field sufficient to effect

movement of the valve mechanism of the implantable device and an acoustic sensor *disposed within the central opening in the housing* and electronically coupled to the transmitter for detecting acoustic signals generated by the valve mechanism during an adjustment cycle.

Porat fails to teach or even suggest the device of claim 20 because it lacks the claimed extracorporeal housing. As shown in FIGS. 10-11 of Porat, the extracorporeal portion of the Porat system consists only of a helmet (310) containing a plurality of acoustic transducers (321) coupled to an extracorporeal station (130) that processes the transducer output. Claim 20 requires that the extracorporeal housing have a central opening, however neither the helmet (310) nor the station (130) of Porat are disclosed as having such an opening. Moreover, claim 20 requires an acoustic sensor disposed within said central opening. Although Porat teaches a plurality of transducers (321), none are disposed within a central opening of a housing as claimed, much less electronically coupled to a transmitter contained within the housing having a plurality of electromagnetic coils, as also claimed. To the contrary, the Porat transducers (321) are dispersed peripherally throughout the helmet (310). And since Porat has no teaching of a transmitter with electromagnetic coils whatsoever, much less a teaching of such a transmitter being contained within the helmet (310), the Porat transducers (321) cannot possibly be electrically coupled thereto. Porat thus fails to teach or suggest several features of the claimed housing.

Porat is also deficient with respect to claim 20 because it lacks an acoustic sensor for detecting acoustic signals *generated by a valve mechanism during an adjustment cycle*. First, there is no teaching that Porat's valve (105) has any adjustable settings at all, much less that it emits acoustic signals while being adjusted. Rather, the only acoustic signals in Porat are generated by a transducer (114), not a valve as claimed. *See, e.g., Porat* at col. 15, ll. 51-54. Second, even if the Porat valve (105) did produce an acoustic signal, the biosensor (100) relied upon by the Examiner to form the claimed sensor *would not be capable* of detecting it because of the large distance between the valve (105) and the biosensor (100). In other words, the location of the biosensor (100) within the patient's brain would prevent it from detecting subtle noises generated by a valve (105) located several inches away in the patient's neck. *See Porat* at FIG. 11. Porat thus lacks an acoustic sensor for detecting acoustic signals generated by a valve mechanism during an adjustment cycle, as further required by claim 20.

Furthermore, it would not have been obvious to somehow combine Porat and Hakim to arrive at the claimed invention. At the outset, Hakim is likewise deficient with respect to claim 20 because it too lacks a housing having a central opening with an acoustic sensor disposed therein. In fact, Hakim has no teaching of an acoustic sensor whatsoever. Hakim thus necessarily lacks the claimed acoustic sensor electronically coupled to a transmitter as well.

Even if, however, the references were somehow construed to collectively include the requisite claim limitations, no motivation exists to combine the two. "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." *MPEP* § 2141(III). The Supreme Court in *KSR Int'l Corp. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), stated that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." There is no teaching in either Porat or Hakim that would lead a person having ordinary skill to modify the Hakim valve adjustment mechanism (390) to include the transducers (321) of Porat. The only purpose for the transducers (321) in Porat is to communicate via acoustic waves with a corresponding set of acoustic transducers (114) and physiological sensors (112) implanted in a patient. Since Hakim has no such implanted transducers or sensors, the external Porat transducers (321) would be useless when applied to the Hakim device and no skilled artisan would be motivated to make such a combination.

In addition, claim 20 requires an acoustic sensor *disposed within a central opening in a housing*, yet Porat expressly teaches away from having the transducers (321) disposed in a central opening as claimed, instead teaching that "[h]elmet 310 includes a plurality of transducers 321,... positioned at various locations so as to provide full transmittance/reception spatial coverage of the brain volume." *Porat* at col. 20, ll. 31-35 (emphasis added); *see also Porat* at FIG. 11. In other words, Porat teaches that there should be a plurality of transducers dispersed peripherally about the helmet so as to get maximum signal coverage. A person of ordinary skill in the art using Porat as a guide would thus seek to spread the sensors out across the device, not place them in a central opening as claimed. *MPEP* § 2145(X)(D)(2) clearly states that "[i]t is improper to combine references where the references teach away from their combination. In *re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)." The Supreme Court similarly held in *KSR v. Teleflex* that "[w]hen the prior

art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR v. Teleflex*, 127 S. Ct. 1727, 1740 (2007) (citing *United States v. Adams*, 383 U.S. 39 (1966)). Since Porat expressly teaches away from the claimed sensor disposed within a central opening in a housing, an obviousness rejection based thereon is improper.

Accordingly, for at least the reasons discussed herein, claim 20 is not obvious in view of Porat or Hakim, taken alone or combined, and therefore represents allowable subject matter. Claims 22, 24-34, and 36 are non-obvious and allowable at least because they depend from claim 20.

*Claim 37*

Independent claim 37 recites an acoustic monitoring system for verifying the pressure setting of a valve mechanism in an implantable device having a plurality of adjustable valve settings. The system includes an extracorporeal device for adjusting an opening pressure of the valve mechanism and an extracorporeal transmitter *having a central opening formed therein* and configured to generate an energy field sufficient to cause movement of the valve mechanism. The system also includes an acoustic sensor *disposed within the central opening in the transmitter* and electrically coupled to the transmitter for detecting acoustic signals generated by the valve mechanism during an adjustment cycle, wherein the transmitter communicates the detected acoustic signal to the device for analysis.

For the same reasons discussed above with respect to claim 20, Porat and Hakim both fail to teach or even suggest a transmitter having a central opening formed therein and an acoustic sensor disposed within the central opening. In addition, no obvious combination of the two references exists. Accordingly, claim 37 is not obvious over Porat or Hakim, taken alone or combined, and represents allowable subject matter.

***Claim Rejections Pursuant to 35 U.S.C. § 103(a) – “Porat, Hakim, Ericson, and Greeninger”***

Dependent claims 31, 33-34, 36, and 38-40 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Porat in view of Hakim and further in view of U.S. Patent No. 6,533,733 (“Ericson”) and still further in view of U.S. Patent No. 6,082,367 (“Greeninger”). Each of these secondary references is merely relied on to teach discrete features recited in the dependent claims, and neither reference remedies the deficiencies of Porat and Hakim discussed above with respect to

the independent claims. Claims 31, 33-34, 36, and 38-40 are therefore non-obvious and allowable at least because they depend from allowable base claims.

***Conclusion***

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

Date: September 25, 2009

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